

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES,)	
LLC,)	
)	
Plaintiffs,)	
)	
v.)	
)	Civil Action No. 04-968 (GMS)
ALCON INC., ALCON LABORATORIES,)	
INC., and ALCON RESEARCH, LTD.,)	
)	
Defendants.)	

ORDER

1. Allergan, Inc. and Allergan Sales, LLC (collectively, “Allergan”) filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, “Alcon”) on August 24, 2004. Allergan filed this suit for patent infringement pursuant to 35 U.S.C. § 271(e)(2).¹ The complaint alleges that Alcon infringes U.S. Patent No. 6,673,337 (the “337 patent”) and U.S. Patent No. 6,641,834 (the “834 patent”) because it submitted a § 505(b)(2) application, or paper New Drug Application (“paper NDA”), to the Food and Drug Administration (“FDA”),

¹ Section 271(e)(2) states, in pertinent part:

[i]t shall be an act of infringement to submit – an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

seeking approval of its proposed generic brimonidine tartrate ophthalmic drug product.² (Compl. ¶¶ 14-15, 17.) The complaint further alleges that Alcon acted without a reasonable basis for believing that it would not be liable for infringement of the '337 and '834 patents and, as such, its infringement of the '337 and '834 patents is willful. (*Id.* ¶¶ 19, 23.) Allergan requests injunctive relief and attorney's fees, pursuant to 35 U.S.C. § 285.³ The issue presently before the court is whether Allergan may assert a claim for willful infringement.

2. Allergan contends that a willfulness claim is proper based on the totality of the circumstances. Allergan further contends that the totality of the circumstances comprises many factors, including whether Alcon intentionally copied ALPHAGAN® P, whether Alcon exercised due care to avoid infringing Allergan's patents, whether Alcon relied on competent legal advice, and Alcon's behavior as a party to the litigation. (D.I. 64, at 2.) According to Allergan, its claim of willfulness is based the following: (1) Alcon's Paragraph IV certification was filed without reasonable basis; and (2) Alcon's conduct in the litigation demonstrates its lack of reasonable basis. (*Id.* at 3). Lastly, Allergan contends that the Federal Circuit's holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) does not foreclose a claim for willful infringement in Abbreviated New Drug Application ("ANDA") or paper NDA cases. (*Id.*)

² Alcon also filed a certification with the FDA under 21 C.F.R. § 314.50(i)(1)(i)(A)(4), or Paragraph IV Certification, alleging that the '337 and '834 patents are invalid and/or not infringed by its product.

³ Section 285 provides: "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." The Federal Circuit has recognized willful infringement as a type of misconduct that creates an exceptional case. *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1365 (Fed. Cir. 2000) (citing *Beckman Instruments, Inc. v. LKB Produkter AB*, 894 F.2d 1547, 1151 (Fed. Cir. 1989)).

3. Alcon asserts that the only act of infringement alleged in the complaint is the filing of its paper NDA with the FDA. According to Alcon, in light of the Federal Circuit's holding in *Glaxo*, "Allergan's conclusory allegation – standing alone – cannot support a charge of willful infringement." (D.I. 75, at 2.)

4. The Federal Circuit first addressed the issue of willfulness in ANDA and paper NDA cases in *Yamanouchi Pharm. Co., Ltd. v Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir 2000). In *Yamanouchi*, the court found that "[a]n ANDA [or paper NDA] filing by its very nature is a 'highly artificial act of infringement,' therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." 231 F.3d at 1347. Nonetheless, the court held that the case was exceptional and awarded attorney fees to the plaintiff, based on the defendant's "misconduct in filing a wholly unjustified ANDA certification and misconduct during the litigation that followed. . . ." *Id.*

5. The Federal Circuit addressed the issue again in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), holding that "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." 376 F.3d at 1350-51. In the *Glaxo* opinion, the court explained that in *Yamanouchi* it "determined that a baseless and 'wholly unjustified' paragraph IV certification in an ANDA filing, when combined with litigation misconduct, warranted an exceptional case finding." *Id.* at 1350. According to the court, "in *Yamanouchi* we did not agree that the generic company had engaged in willful infringement, but rather determined that an award of attorney's fees was permitted because the generic had filed numerous baseless filings supporting its fruitless and meritless arguments, both in its case at trial and in its ANDA certification." *Id.*

6. In the present case, Allergan has not pointed to anything which would support a finding of willful infringement. The only act of infringement alleged in Allergan's complaint is Alcon's allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA. Because a paper NDA filing cannot be considered willful, Allergan's complaint does not state any basis under which it could assert a claim for willful infringement. Allergan, however, maintains that Alcon's change in position with respect to its written description defense set forth in its summary judgment motion, combined with the paper NDA filing, permits a claim for willful infringement. The court disagrees. As the Federal Circuit explained in *Glaxo*, a finding that a ANDA/paper NDA case is "exceptional" can be based on meritless filings combined with litigation misconduct, but a finding of willful infringement cannot. Accordingly, the court will not permit a claim for willful infringement in this case. That being said, the court will not foreclose Allergan from, at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case for which the court should award attorney's fees. *See Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc.*, 355 F. Supp. 2d 586, 592-93 (D. Mass. 2005).

Therefore, IT IS HEREBY ORDERED that:

1. A claim for willful infringement is not permitted in this case.
2. Allergan's claim for willful infringement shall be stricken from the complaint.

Dated: July 26 , 2005

/s/ Gregory M. Sleet
UNITED STATES DISTRICT JUDGE

EXHIBIT D

1

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF NEW JERSEY
3 CIVIL ACTION NO. 3:04-1689 (MLC)

3

4 ORTHO-McNEIL PHARMACEUTICAL, INC., ORAL ARGUMENT

5 Plaintiff and
6 Counterclaim Defendant,

7 vs.

8 MYLAN LABORATORIES, INC. and
9 MYLAN PHARMACEUTICALS, INC.,

10 Defendant and
11 Counterclaim Plaintiffs

12 April 18, 2005
13 Trenton, New Jersey

14 B E F O R E: HONORABLE STANLEY R. CHESLER, USDJ

15

16

17 Pursuant to Section 753 Title 28 United States Code, the
18 following transcript is certified to be an accurate record
as taken stenographically in the above-entitled proceedings.

19 JACQUELINE KASHMER
20 Official Court Reporter

21

22

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1 THE COURT: Ortho-McNeil Pharmaceutical vs. Mylan.

2 Can I have appearances by counsel please.

3 MR. ROPER: For Ortho-McNeil, Harry Roper, Aaron
4 Barlow and Eric Lohrenz.

5 MR. MIDDLETON: And also John Middleton from
6 Lowenstein Sandler, your Honor.

7 THE COURT: Good morning.

8 MR. CALMANN: Arnold Calmann, Saiber, Schlesinger,
9 Satz & Goldstein, for the defendants, Mylan, and with, me
10 your Honor, are my co-counsel David Harth and Shannon
11 Bloodworth from the Heller Ehrman firm.

12 THE COURT: Good morning to you. We will first
13 take the motion to dismiss the willful infringement claim
14 I'll hear from counsel for movant.

15 MR. HARTH: Thank you, your Honor. The motion
16 simply asks the Court to apply recent binding-Federal
17 Circuit precedent that the filing of an ANDA application or
18 certification cannot support a finding of willful
19 infringement.

20 The Federal Circuit in the Glaxo case held that
21 willfulness cannot provide the basis for the filing of an
22 ANDA certification, cannot provide the basis for a
23 willfulness claim.

24 The plaintiffs here have contended that Glaxo does
25 not apply because in that case the defendant had not filed a

1 Paragraph 4 certification, which is what happened here, but
2 the Federal Circuit crafted its holding in Glaxo
3 specifically to cover Paragraph 4 certifications.

4 In that case the Federal Circuit held, quote, "The
5 mere fact that a company has filed an ANDA application or
6 certification cannot support a finding of willful
7 infringement for the purpose of awarding attorney's fees
8 pursuant to 35 U.S.C. Section 271", and the Federal Circuit
9 did so on the basis of the Yamanouchi case, which was a
10 Paragraph 4 certification.

11 Since the Federal Circuit's decision in Glaxo, the
12 precise issue that's presented here was decided by the
13 District of Massachusetts in Aventis vs. King
14 Pharmaceuticals, and prior to the last hearing we had sent
15 Judge Cooper a letter with that case. Is that in the
16 Court's file?

17 THE COURT: I do have the Aventis vs. Cobalt
18 Pharmacy.

19 MR. HARTH: Well, Aventis rejected the very
20 argument that Ortho-McNeil is making here holding that the
21 words "or certification" in the Federal Circuit's Glaxo
22 decision was not mere surplusage, that it did cover
23 Paragraph 4 certification cases, and for that reason there
24 could be no willfulness claim in a Paragraph 4 certification
25 case, either.

1 We think that the District of Massachusetts got it
2 right. We think that the Federal Circuit's language is
3 unambiguous in that regard and for that reason, the
4 willfulness claim should be dismissed.

5 THE COURT: Let me hear from counsel for the
6 plaintiffs.

7 MR. ROPER: Harry Roper for the plaintiffs, your
8 Honor. I think that our position on this Glaxo case is not
9 controlling. This has not been definitively ruled upon by
10 the Federal Circuit because in Glaxo there was no Paragraph
11 4 certification.

12 Here our whole contention is that the Paragraph 4
13 certification is so baseless and the lawsuit is so baseless
14 that the infringement which is virtually admitted is
15 willful.

16 The Massachusetts case that they cite, of course,
17 is not precedential because the Federal Circuit hasn't ruled
18 on it. So, that being said, your Honor, this is a bench
19 trial. I think this law may develop further in the Federal
20 Circuit and my suggestion is that your Honor defer this
21 entire thing and we see how that law develops.

22 Basically, our contention here is that in light of
23 this case, we are entitled to attorney's fees one way or the
24 other in this case and either it's willful infringement or
25 it's under the statute and we are entitled to them. And we

1 are entitled to discovery. Whether that discovery gets
2 bifurcated or not is not important. But I think
3 fundamentally we don't see any reason why there can't be a
4 willful infringement case in ANDA litigation.

5 THE COURT: So, your argument is that the Fed
6 Circuit's opinion in Glaxo vs. Apotex, where they say,
7 quote, "Consequently, as suggested by Yamanouchi, we now
8 hold that the mere fact that a company has filed an ANDA
9 application or certification cannot support a finding of
10 willful infringement for purposes of awarding attorney's
11 fees pursuant to 35 U.S.C. Section 271(e)(4). The Supreme
12 Court has emphasized that 35 U.S.C. Section 271(e)(2) and 35
13 U.S.C. Section 271(e)(4) create a 'artificial act of
14 infringement' only for a 'very limited and technical
15 purpose' that relates only to certain drug applications."

16 MR. ROPER: Two reasons.

17 THE COURT: Why would a poor soul like me working
18 in the trenches conclude that the Federal Circuit didn't
19 mean what they said there?

20 MR. ROPER: They did mean what they said there.

21 THE COURT: Okay.

22 MR. ROPER: And they say the mere fact that you
23 filed ANDA, that's different than filing a baseless ANDA,
24 number one, and it's certainly different than filing a
25 baseless Paragraph 4 certification, which they didn't even

1 deal with In that case, so, our facts are different than

2 Glaxo for those two reasons, your Honor.

3 THE COURT: Okay. I must tell you that as

4 interesting as I find your argument, I find that it goes

5 fundamentally against the underlying rationale of the Fed

6 Circuit's decision in the Glaxo case.

7 Their emphasis was on the fact that this whole

8 Hatch-Waxman process exists for a very limited purpose of

9 creating a technical infringement so that a case or

10 controversy under the Constitution can exist whereby United

11 States district courts and other folk who decide these cases

12 can actually decide whether or not the proposed generic

13 drug, if manufactured, would infringe. And as I read the

14 Glaxo case, it's saying where the whole reason that we, in

15 fact, permit a case to go forward as an infringement case

16 because of this technical infringement is to permit the

17 matter to be decided before the drug gets on the market;

18 that the mere filing of that ANDA application or

19 certification can't constitute a willful infringement.

20 What the court in Glaxo makes clear, as I

21 understand, is that doesn't mean that the plaintiff can't

22 apply for attorney's fees but they're not applying for

23 attorney's fees on the basis of a willful infringement.

24 They're applying for attorney's fees on the basis of it

25 being, I believe it would be an extraordinary case. Is that

1 correct?

2 MR. ROPER: Yes, your Honor, that's correct.

3 THE COURT: And as I understand it, in Glaxo they
4 said, go ahead, go for it under that standard but not under
5 a willful infringement standard. Correct?

6 MR. ROPER: Yes, your Honor. Except that they
7 didn't deal, as I said, with the specific facts that we have
8 here.

9 THE COURT: Go ahead. I'm sorry.

10 MR. ROPER: And your Honor, and indeed, as I said,
11 that our only position here is to preserve our right to seek
12 those attorney's fees one way or the other and, to be quite
13 frank, your Honor, if your Honor would permit, we would
14 withdraw the actual willfulness claim as long as we're
15 permitted to continue to seek discovery and continue to
16 pursue the claim under the statute.

17 THE COURT: Well, there's no doubt that you can
18 seek to pursue attorney's fees under an extraordinary case
19 standard, I must tell you, all right, but -- and I
20 understand exactly where you're going, all right, and the
21 short answer is no. Okay.

22 I will tell you, if the issue is can we engage in
23 all sorts of discovery for a willful infringement standard
24 because -- let me put it this way -- because if willful
25 infringement stays in the case, then they're going to assert

1 a defense of reasonable reliance of advice of counsel and
2 then we can say we get the right to take a look at all your
3 opinion letters and so on and so forth because there's a
4 reliance on advice of counsel defense. Correct?

5 MR. ROPER: Your Honor, can I make a comment on
6 that specifically?

7 THE COURT: Yes.

8 MR. ROPER: It's a good point. Your Honor, there
9 is a dispute right now, a discovery dispute with regard to
10 whether we are entitled to get their counsel's opinion for
11 this reason; that during testimony there was a lot of -- I
12 don't want to argue the motion to get the opinion --

13 THE COURT: That's good because the magistrate
14 judge is going to be hearing that particular application.

15 MR. ROPER: And we are going to present -- and we
16 will present that to her. It's been discussed by the
17 parties but we are going to be presenting it to her and
18 that's for that. So, and we are satisfied to live with that
19 ruling.

20 I'm not seeking anything other than that. We would
21 be happy to live with that ruling without regard to
22 willfulness, simply with regard to waiver.

23 THE COURT: Okay. First, I'm satisfied that
24 Glaxo's language is not mere surplusage and to the extent
25 that the Glaxo opinion contains the word "or certification"

10

1 is dicta. The Court will regard it as dicta which gives a
2 very clear and forceful direction to the district court as
3 to how the Federal Circuit views this particular claim.

4 The Court is satisfied that the Glaxo opinion of
5 the Fed Circuit, indeed, as interpreted by U.S. District
6 Court for the District of Massachusetts in Aventis Pharma
7 Deutschland GMBH and King Pharmaceuticals vs. Cobalt
8 Pharmaceuticals reported at 2005 Westlaw 289835, in fact,
9 correctly interprets Glaxo and the willful infringement
10 claim is dismissed. Okay.

11 And by the way, what I was saying is that I
12 sometimes sit and for some reason I'm amazed at what is
13 almost a prurient interest which patent counsel have in
14 looking at the opinions of each other and while I understand
15 the curiosity, the Court nevertheless does not have to
16 encourage it. Okay.

17 MR. ROPER: Thank you, your Honor.

18 THE COURT: Now, we've got a motion for summary
19 judgment. Correct?

20 MR. HARTH: We do, your Honor.

21 THE COURT: All right. And in the first instance
22 that hinges on a Markman interpretation. Correct?

23 MR. HARTH: Yes, your Honor.

24 THE COURT: Okay. Let me hear you.

25 MR. HARTH: This basically is the Markman part of

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ORTHO-McNEIL PHARMACEUTICAL, INC.,	:	Hon. Stanley R. Chesler Civil Action No. 04-1689
Plaintiff	:	
v.	:	
MYLAN LABORATORIES, INC., et al.,	:	ORDER
Defendants.	:	

CHESLER, U.S. District Court Judge

THIS MATTER comes before the Court upon Defendants' Motion for Judgment on the Pleadings Dismissing Plaintiff's Claim of Willfulness (docket item #16), and Defendants' Motion for Summary Judgment of Non-Infringement(docket item #22). The Court having considered the papers submitted by the parties, having heard oral argument, and for the reasons set forth in the record of oral argument on April 18, 2005;

IT IS on this 18th day of April 2005:

ORDERED that Defendants' Motion to Dismiss Plaintiff's Claim of Willfulness is **GRANTED**; and it is further

ORDERED that judgment is **RESERVED** on Defendants' Motion for Summary Judgment; and it is further

ORDERED that the parties are directed to contact the Court to schedule a Markman hearing.

s/
STANLEY R. CHESLER
U.S. District Court Judge

CERTIFICATE OF SERVICE

I caused a true and correct copy of the foregoing documents to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filings to the following:

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